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Mr Joop Atsma
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Dear Secretary of State,

Thank you for your letter of 6 July 2012, in which you and colleagues from Austria, Czech Republic, Denmark, France, Italy, Luxembourg, Spain, Sweden and Croatia raise a number of issues concerning an EU level response to ensure the safety of nanomaterials. We apologise for the delayed reply.

The Commission shares your view that the EU needs a coherent, safe, and responsible approach to nanomaterials, which will ensure consumer trust and a high level of protection of human health and the environment, while at the same time not stifling innovation in this Key Enabling Technology. This will be crucial to maintain the competitiveness of the European industry, especially in the current economic situation.

As requested in your note, the Commission has conducted a comprehensive review of all the aspects raised by the Parliament in its resolution of 24 April 2009, as well as others brought forward by the Council and the European Economic and Social Committee. The results of the review as well as the Commission's proposals for future action and the rationales behind the proposals were presented on 3 October in a Communication on the Second Regulatory Review on Nanomaterials to the European Parliament and the Council. It is accompanied by a Staff Working Paper on Nanomaterial Types and Uses, including safety aspects.

The Commission considers that nanomaterials are similar to normal chemicals/substances as regards risk assessment in that some may be hazardous and some are not. Possible risks are related to specific nanomaterials and specific uses and require a case by case risk assessment.

The Commission agrees with the recent OECD conclusion that current risk assessment methods for chemicals are generally applicable also to nanomaterials, even if further work on particular aspects is still required.

Overall the Commission remains convinced that REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or in mixtures. However, an ex-post assessment of registration dossiers with nanomaterials has shown that some of the current technical provisions need to be made more specific for nanomaterials. Therefore, as you also note in your letter, the Commission envisages assessing in the upcoming REACH review relevant regulatory options, in particular possible amendments of REACH annexes, to ensure clarity on how nanomaterials are addressed and safety demonstrated in registrations. Moreover, ECHA is encouraged to further develop guidance for registrations. ECHA has already set up two specific advisory groups to identify best practices based on the experience with already registered nanomaterials and develop recommendations on how to fill potential information gaps.

The Commission has paid particular attention to assess whether other legislation should be reviewed. Challenges relate primarily to establishing validated methods and instrumentation for detection, characterization, and analysis. Where gaps are identified, the Commission envisages addressing them with recommendations for follow-up action, which will be undertaken subsequently.

As regards consumer product safety legislation, work is under way on adapting legislation to incorporate, when appropriate, the horizontal definition of nanomaterials and specific provisions on nanomaterials, on updating the relevant risk assessment processes, on strengthening market surveillance, and on improving information and labelling requirements.

The Commission agrees that transparency of information on nanomaterials and products containing nanomaterials is essential. The review has revealed that the vast majority of applications are dominated by materials which have been in use for decades, such as carbon black or synthetic amorphous silica, which are used in tyres or as polymer fillers, and, in the case of synthetic amorphous silica, also in foods, food contact materials and non-food products.

There are a growing number of more recent and innovative applications, mostly in technical products such as catalysts, electronics, batteries, solar panels etc., which are essential for maintaining the competitiveness of the European industry and contribute to resolving many environmental and societal challenges identified in the EU2020 strategy. To increase knowledge about new applications, the Commission envisages creating, as a first step, a web platform in 2013 with references to all relevant information sources, including registries on a national or sector level, where they exist. A first version mainly based on links to available information will be put on line as soon as possible. The Commission will assist in the elaboration of harmonised data formats, to improve exchange of information. In parallel, the Commission will be launching an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight, including an in-depth analysis of the data gathering needs for such purpose. This analysis will include those nanomaterials currently falling outside existing notification, registration or authorisation schemes.

The share of EU funded nano research dedicated to studies on the potential adverse effects of nanomaterials on human health and on the environment has increased regularly since FP6, to reach about 35 Mio Euro of commitment this year. In FP7, it is over 10% of the whole nanotechnology funding budget which is specifically committed to nanoEHS topics (140M€ so far), making it the most funded area in the NMP programme. These figures neither include nanomedicine topics, which provide very useful know-how for nanosafety, nor the rest of EHS activities in product-oriented projects.

On top of this, as you are undoubtedly aware, the Commission and the Member States have examined the possibility of using existing tools for research funding to launch an action combining efforts in the domain of toxicity-ecotoxicity testing and exposure control of nanomaterials in support of regulation. As a result of the last NMP call (published July 2011) the proposal NANOREG, coordinated by the Dutch *Ministerie van Infrastructuur en Milieu*, is under negotiation (expected to start early next year), and puts together EC, MS governments, Industry and Laboratories funds approaching 50 M€ with EC funding of 10 M€.

Ensuring the safe and responsible development and application of nanotechnologies is one of the main lines of activity proposed in Horizon 2020. Research concerning safety and the development of reliable test methods will remain key priority under the EU Framework Programmes and for the Commission's Joint Research Centre.

Yours faithfully,

Antonio Tajani — Janez Potočnik — Máire Geoghegan-Quinn